



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 16 1999 2782 '99 AUG -3 P3:27

Mr. Marwan Zreik
Director of Research & Development
Naturade, Inc.
7110 Jackson Street
Paramount, California 90723

Dear Mr. Zreik:

This is in response to your letter of June 23, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). In your letter, you state that Naturade, Inc. is making various claims for the product **The Chinese Way™ Cholesterol Support Formula**. This product contains the ingredient red yeast rice, fermentation of *Monascus purpureus*.

This letter is to advise you of the current status of products that contain red yeast rice. FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin¹", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the FD&C Act. This decision meant that Cholestin could not be legally sold in the United States.

On February 16, 1999, the United States District Court for the District of Utah "held unlawful and set aside" the FDA's administrative finding of May 20, 1998. FDA has appealed the District Court's decision to the United States Court of Appeals for the 10th Circuit. The future regulatory status of all red yeast rice products will depend, in part, on the decision of the courts on the merits of the Cholestin matter. At this time, FDA believes that products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

¹Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

for Robert M. Moore
Lynn A. Larsen, Ph.D.

Director

Division of Programs and Enforcement Policy

Office of Special Nutritionals

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

Page 3 - Mr. Marwan Zreik

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

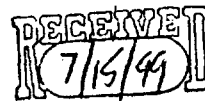
GCF-1 (Dorsey, Barnett, Nickerson, Parker)

HFV-228 (SBenz)

f/t:HFS-456:rjm:7/16/99:docname:66088.adv:disc38



MANUFACTURERS & DISTRIBUTORS
OF NUTRITIONAL PRODUCTS



June 23, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Naturade, Inc., located at 14370 Myford Road, Irvine, CA 92606, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM

"With Red Yeast Rice to promote healthy cholesterol levels"

"Rich in Vitamin B6 and Folic Acid to lower homocysteine levels"

"With *Chinequalize*TM herbal base to help maintain your natural balance"

"The Chinese Way's Cholesterol Support Formula is an all natural supplement designed to help promote healthy cholesterol levels. The Red yeast Rice (Xuezhikang) in this product is a naturally derived Chinese herb which has been shown to be effective in helping to regulate the production of cholesterol. Vitamins B6 and Folic Acid promote heart health by regulating the production of homocysteine."

NAME OF INGREDIENT OR SUPPLEMENT THAT IS SUBJECT OF CLAIM

Vitamin B6 (as pyridoxine hydrochloride)

Folate (as folic acid)

Monascus purpureus (Chinese Red Yeast) Rice

Fo-Ti Root Powder (*Polygonum multiflorum*)

Garlic Powder (Odor modified; *Allium sativum*)

Proprietary Blend:

Schizandra chinensis (berry powder), *Astragalus membranaceus* (root powder),
Codonopsis tangshen (root powder), *Lycium chinensis* (fruit powder), *Rehmannia glutinosa* (root powder)

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MANUFACTURERS & DISTRIBUTORS
OF NUTRITIONAL PRODUCTS

NAME OF SUPPLEMENT

The Chinese Way™

Cholesterol Support Formula

The undersigned certifies that the information contained in this notice is complete and accurate and that Naturade, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

Marwan Zreik, MS, CCN

Director of Research & Development